

**Method for Determining Care and Prevention Pathways for
Clinical Management of Wounds**

5 This application is related to co-pending application number 60/116,349 (filed January 19, 1999), which is incorporated herein by reference in its entirety.

 The present invention relates to methods for consistently designating appropriate treatment protocols for patients, particularly protocols involving wounds or wound prevention.

10 A number of computer programs have been developed wherein a user, for example a care giver, inputs parameters indicative of a patient assessment into a computer and obtains a care plan as an output. Input parameters can include art recognized assessment parameters, such as those recommended by the National Pressure Ulcer Advisory Board. One example of such a computer program is the Wound and
15 Skin Intelligence System (WSIS) developed by Convatec and Applied Health Sciences. Other similar programs have been developed by Johnson & Johnson Medical (a division of Ethicon, Inc.) and Smith & Nephew, Ltd.

 The effective use of such computer-based methods of deriving care plans often requires simultaneous proximity of the care giver to both the patient and the computer.
20 Care givers without ready access to a patient in close proximity to the programmed computer cannot effectively benefit from such computer-based approaches. Moreover, even when the programmed computer is available, the practicalities of providing care often makes it awkward to input data prior to rendering a treatment protocol.

 Accordingly, there is a need for a method of selecting care plans for patients
25 customized to clinical assessment parameters that does not require immediate interaction with a computer, without compromising the quality of care provided. The present invention provides a method for correlating patient assessment parameters with appropriate treatment protocols. The method provides a visually keyed process to derive a care plan. The process does not require a computer, and when executed with a
30 computer is highly integrated with visual cues. Such a process can be embodied in devices that provide bedside tools to assist the care giver to make evidence-based decisions for the care of individuals, such as individuals at risk of forming wounds or individuals who already have wounds, such as a pressure ulcers.

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Summary of the Invention

In one embodiment, the invention relates to a method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising: classifying the wound or patient against a defined scale for a first wound factor, which is defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification; grading the wound or patient against defined scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors; and operating a visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors. In some embodiments, at least one visual decision tree indicates two or more distinct decisions based on the grade of one or more second wound factors. In some embodiments, the visual decision tree is a mechanical device. In some embodiments, the method can also comprise providing an interactive visual scoring sheet on which markers for the available scores for two or more wound factors are displayed; and marking the appropriate score for the two or more wound factors on the interactive visual scoring sheet, wherein the interactive visual scoring sheet contains a marker associated with one or more of the scores identifying an addition to the treatment protocol.

In some embodiments, the invention relates to a method comprising classifying the wound against a defined wound classification scheme; grading the wound against defined scales for one or more second wound assessment factors; and operating visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a grade for a wound assessment factor, wherein at least one visual decision tree produced by the device dictates two or more distinct decisions based on the grade of one or more second wound assessment factors, and wherein the visual decision device identifies a treatment protocol for the wound classification and grades of the second wound assessment factors. In some embodiments of the invention, one of the two visual decision tree devices is selected based on wound classification, and the selected visual decision tree device is operated to show a decision or decision tree corresponding to a grade for exudate amount. In some embodiments, the wound

classification scheme grades wounds from non-open or closed wounds, to wounds of various thicknesses, to wounds that cannot be graded due to obstructions.

The invention, in some embodiments, relates to a method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising: classifying the wound or patient against a defined scale for a first wound factor, which is defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification; grading the wound or patient against defined scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors; operating visual decision tree device to show the visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein at least one visual decision tree dictates two or more distinct decisions based on the grade of one or more second wound factors, and wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors; and marking a pre-defined display of treatment protocols to identify the components of a treatment protocol identified by the method. In some embodiments, the method of the invention is operated through a graphical user interface on an electronic processor, resulting in a display of treatment protocols that matches a printed display used in manual operations of the method.

The invention also relates to a visual decision tree device for identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising: a mechanical or electronic device for identifying and displaying one of at least two decisions or visual decision trees based on one or more inputted wound factors according to a defined scale, wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors. In some embodiments, the sliding card comprises markers corresponding to a defined scale for classifying the wound or patient. In some embodiments, one or more sliding cards shows a visual decision tree and wherein the housing comprises a view window through which one or more visual decision trees corresponding to the wound classification can be viewed. In some embodiments, the visual decision tree device is mechanical and wherein the slide card can be moved with respect to the housing to view through the view window any one of a plurality of individual decision trees displayed on the sliding card.

Brief Description of the Drawings

Figure 1 displays a wound assessment interactive visual scoring sheet.

Figure 2 displays a chronic wound management decision tool, which is a type of portable mechanical slide-rule visual decision tree device.

5 **Figure 2A** displays a schematic of a slide-rule visual decision tree device.

Figure 2B displays a first set of two exemplary sliding cards.

Figure 2C shows a second set of two exemplary sliding cards.

Figure 3 displays a schematic of a modular wound care protocol sheet.

Figure 4 displays a Patient Risk Assessment and Nurse Action Record, which is
10 a type of interactive visual scoring sheet.

Figure 5 displays a Patient Risk Assessment Evaluation Tool, which is a type of portable mechanical slide-rule decision tree device.

Figure 5B displays a third set of two exemplary sliding cards.

Figure 6 displays a modular wound prevention protocol sheet.

15 **Figure 7** displays a Wound Care and Assessment Record.

Figure 8 displays a pressure ulcer pathway decision tool, which is a type of a portable mechanical slide-rule visual decision tree device.

Figure 9 displays a wound assessment interactive visual scoring sheet.

Figure 10 displays a chronic wound management decision tool, which is a type
20 of portable mechanical slide-rule visual decision tree device.

Figure 11 displays a Wound Care and Assessment Record.

Detailed Description of the Invention

FIG. 1 relates to an interactive visual scoring sheet **10** that can be used according to a preferred embodiment of the present invention. The interactive visual scoring sheet **10** can take substantially the same visually-cued form on the screen of a computer or personal device assistant (PDA). In electronic form, each scoring choice is separately on a viewing screen represented as in the paper example illustrated in FIG. 1. The interactive visual scoring sheet **10** comprises a first defined scale **11** for classifying or grading a wound or patient according to a first wound factor **12** and a second defined scale **13** for classifying or grading the wound or patient for one or more second wound factors **14**. In some embodiments, the second defined scale **13** can include classifying or grading of the wound or patient according to: a defined wound assessment factor, a

defined wound risk assessment factor, some other classification of a patient's condition, or any combination of such factors. The first defined scale **11** and the second defined scale **13** can be represented by one or more markers **19** corresponding to one or more stages, grades or classifications. Markers **19** and associated criteria **15** can be indicated on the visual scoring sheet **10**, for example, by indicia associated with markers **19**, including varying colors, numbers, letters, symbols, texture or any combination thereof. Optional associated criteria is provide a brief indication of the classifying or grading criteria. In some embodiments, the appropriate score for one or more classifying or grading factors can be marked on the interactive visual scoring sheet **10**. The criteria **15** can be indicated in whole or in part on the visual scoring sheet **10**, or be referenced to criteria found elsewhere. The presence of at least a shorthand reference to the criteria is preferred. The second defined scales **13** can be with respect to one or more second wound factors **14**. Second wound factors **14** can, in some embodiments, be selected from any number of factors including but not limited to: exudate amount, necrotic tissue amount, undermining, color of tissue around wound, granulating tissue, peripheral edema, peripheral induration and pain at wound. In some embodiments, second wound factors **14** can include, but are not limited to: sensory perception, moisture, activity, mobility, nutrition and friction & shear. In some embodiments, as shown in FIG. 9, first wound factors **12** and second wound factors **14** can be selected from the group consisting of: depth, exudate amount, exudate type, necrotic tissue amount, necrotic tissue type, undermining, surrounding skin color, granulation, peripheral edema, peripheral induration, pain at wound, nutrition, infection, edges, epithelization, functional ability, compliance and healthy margin.

The exemplary wound grading factors selected for FIG. 1 are a subset of the exemplary wound grading factors selected for FIG. 9. The selection of the particular factors of FIG. 1 as sufficient to predict patient care protocols represents an embodiment of the invention.

In some embodiments, one or more of the markers **19** for the first wound factor **12** or second wound factor **14** pertaining to a wound or patient condition can be connected by connecting indicia **16** such as lines or arrows that identify one or more treatment protocol components **17**. One or more treatment protocol components **17** may be correlated to one or more markers **19**, for example by connecting indicia **16**, and may be written or referred to on the interactive visual scoring sheet **10**.

The interactive visual scoring sheet **10** can form, include or be used in reference to a visual decision tree **18**. Exemplary decision trees **18** are shown in FIG. 2. The visual decision tree **18** can comprise connecting indicia **16**. The visual decision tree **18** can dictate two or more distinct decisions based on one or both of the first or second defined scales **11**, **13** to identify a treatment protocol component **17** for the classified or graded factors. In FIG. 2, a first set of markers **19a** on a first sliding card **22a** are used to indicate values or stages of the first or second defined scales **11**, **13**. A second set of markers **19b** are used on a second sliding card **22b** to indicate values or stages of the first or second defined scales **11**, **13** in the example illustrated in FIG. 2.

In some embodiments, the first defined scale **11** can grade wounds from non-open or closed wounds, to wounds of various thicknesses, to wounds that cannot be graded due to obstructions.

To assess a wound, the wound is first visually inspected and the particular wound or patient parameters are determined, for example, according to one or more defined scales for classifying or grading **11**, **13**. The wound or patient parameters can then be recorded by marking or indicating them on the interactive visual scoring sheet **10**, for example by checking or circling appropriate markers **19**. Connecting indicia **16** and a visual decision tree **18** can then be used to identify appropriate protocol components **17** corresponding to the indicated markers **19**.

In one preferred embodiment of the invention depicted in FIG. 2, a visual decision tree device **20** is provided. A schematic of a visual decision tree device **20** is provided in FIG. 2A. In the nonlimiting example depicted in FIG. 2, the visual decision tree device **20** is a mechanical slide-rule device made up of a first housing **21A** with a first view window **28A** and a first sliding card **22a**. Hingeably attached to the first housing **21A** is second housing **21B** into which slides a second sliding card **22b**. The user inputs a value for one or more first **12** or second **14** wound factors according to the markers **19a**, **19b** for the first or second defined scales **11**, **13** displayed on the first or second sliding cards **22a**, **22b**, for example by adjusting the position of the appropriate sliding card **22a** or **22b** within the appropriate housing **21A** or **21B** such that an appropriate marker **19a** or **19b** corresponding to the desired input value is displayed in view. Selection of the appropriate housing **21A** or **21B** and slide card **22a** or **22b** is determined in this example by connecting indicia **16** to the "Classification of Wound" score on the visual scoring sheet **10** of FIG. 1.

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the slide rule of second housing **21B** shall be used (FIG. 2). Referring to second housing **21B** of the visual decision tree device **20** of FIG. 2, the score for alpha second defined scale **13a** identifies the position to which the ruler is adjusted. Referring to first and second sliding cards **22a**, **22b** of FIG. 2 and FIG. 2C, in the first sliding card **22a**, one dialed position (e.g., “0” on defined scale **13a** for first sliding card **22a** of FIG. 2C) gives a wound care protocol component **17** depending on the score of beta second defined scale **13c**. Another dialed position (e.g., “2” on defined scale **13a** for second sliding card **22b** of FIG. 2C) depends on the score of delta second defined scale **13d**. Two dialed positions (e.g., “1” or “3” on defined scale **13a** for first sliding card **22a** of FIG. 2C) directly indicate wound care protocol components **17**. Some dialed positions on the second sliding card depend on gamma second defined scale **13b**. Referring to FIG. 1, additional wound care protocol components **17** are identified on the visual scoring sheet **10** by connecting indicia **16** associated with first defined scale **11** and beta, epsilon, zeta, eta and theta wound care protocol components **13B**, **13E-13H** (FIG. 1). Shown in FIGs. **2B** and **2C** are particular exemplary first slide and second slide cards **22c**, **22d** and **22a**, **22b**, (respectively). Some embodiments, for example as shown in FIG. 5 and FIG. 5B, can have a third sliding card **22e** and a fourth sliding card **22f** which can slide independently of each other to align a first marker **19a** or a second marker **19b** with a first view window **28a** and a second view window **28b**, respectively. These exemplary slide cards are shown in FIGs **5B** and **5C**, respectively.

FIG. 2B and FIG. 2C display exemplary sets of first and second sliding cards 22a, 22b which can be used to practice the invention. The sliding cards 22a, 22b include separate visual decision trees 18e-18l that can be aligned with a view window of a housing. Likewise, FIG. 2C displays a set of first and second sliding cards 22a and 22b that include visual decision trees 18m-18t. For example, the first and second sliding cards 22c, 22d of FIG. 2B can be used in the visual decision tree device 20 of FIG. 10. Likewise, the first and second sliding cards 22a, 22b of FIG. 2C can be used in the visual decision tree device 20 of FIG. 2. In FIG. 2B, first and second sliding cards 22c, 22d have markers 19a that correspond to a first defined scale 13a and markers 19b that correspond to one or more second defined scales 13b, 13c, 13d. Similarly, first and second sliding cards 22a, 22b of FIG. 2C have a first set of markers 19a corresponding to a first defined scale 13a, a second defined scale 13b, a third defined scale 13c and a fourth defined scale 13d, which scales are defined for this example in the interactive

visual scoring sheet **10** of FIG. **1**. The example displayed in FIG. **2C** can be used in the visual decision tree device **20** of FIG. **2**.

In preferred embodiments, a patient data sheet **40** can be combined with an interactive visual scoring sheet **10** and a wound care protocol sheet **30** in a patient care
5 into a patient diagnostic tool which can be, for example, a single double sided folder or folded sheet of paper. The patient diagnostic tool can be used in conjunction with one or more visual decision tree devices **20**.

The invention can comprise any number of embodiments, some of which are described in the Figures. In some embodiments of the invention, the interactive visual
10 scoring sheet can have different first defined scale **11** and different second defined scale **12** for wound classifying or grading or patient risk assessment. FIG. **1**, FIG. **4** and FIG. **9** show different visual scoring sheets **10** that can be used to practice the invention. FIG. **2**, FIG. **5**, FIG. **8** and FIG. **10** show different visual decision tree devices **20** that can be used to practice the invention. FIG. **3** and FIG. **6** show different wound care protocol
15 sheets **30** that can be used to practice the invention. FIG. **7** and FIG. **11** show different patient data sheets **40** that can be used to practice the invention. The figures are provided as examples of possible embodiments of elements which may be used to practice the invention, and should not be construed to limit the scope of the invention.

20 **Definitions**

The following terms shall have, for the purposes of this application, the respective meaning set forth below.

- **interactive visual scoring sheet.** An interactive visual scoring sheet is printed or
25 electronic sheet on which scoring choices of wound factors are displayed in a form in which the scores can be visually marked.
- **matching electronic display.** An electronic display of treatment protocols matches a traditionally printed display if the treatment options displayed match.
- **slide rule device.** A mechanical visual decision tree device, which can include, for
30 example, a slide rule or slide wheel device.

• **visual decision tree.** A visual decision tree is a representation of two or more decisions, with the appropriate decision indicated visually based on the score of at least one wound factor.

• **visual decision tree device.** A visual decision tree device is a device, electrical or mechanical, which can provide a visual image of a decision or decision tree based on an inputted wound care or wound prevention assessment value. The device produces two or more separate visual images of a decision or decision tree, including at least one decision tree depending on the input value. With a mechanical device, such as a slide rule or slide wheel, “inputting” comprises adjusting the mechanical device to correspond to the input value.

• **wound factor.** A wound factor is a wound assessment factor for which there is a defined grading scale or a wound risk assessment factor for which there is a defined grading scale.

The following examples further illustrate the present invention, but of course, should not be construed as in any way limiting its scope.

Example 1 - Wound Treatment

One example of a method for assessing the status of a patient and derivation of a care plan, or protocol, for wound treatment is as follows. A front cover of a Wound Care & Assessment Record (FIG 7) can be completed and included to identify the patient and care giver and to record dates and details of treatment, or the like. A Wound Assessment Record (Pressure Sore Status Tool), a type of interactive visual scoring sheet (FIG. 1) is completed by circling appropriate assessment scores for each factor (exudate amount, necrotic tissue amount, undermining, surrounding skin color, granulation, peripheral edema, peripheral induration, and pain). Using the interactive visual scoring sheet of FIG. 1, a care giver, upon examining a wound, classifies the wound as Stage 3 according to the first defined scale for classification. The care giver then assigns the following scores to assessing the wound according to their respective second defined scale for grading the wound: Exudate amount = 3; Necrotic Tissue Amount = 3; Undermining = 2; Color of Tissue Around Wound = 3; Granulating Tissue = 3; Peripheral Edema = 1; Peripheral Induration = 0; Pain at Wound = 4.

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Returning to the visual scoring sheet results in the above example, the horizontal arrow horizontally intersecting marker 3 for classification of wound and pointing to "Nurse Action 5" indicates that the care giver should also perform Nurse Action 5 (which is found in Section 5 of Table 1).

- 5 Next, the care giver can examine each marker indicated in the grading scales (from "Exudate Amount" down to "Pain @ Wound") and look for horizontal arrows passing through a marker. For instance, the marker for "3" indicated for "Necrotic Tissue Amount" has an arrow pointing to "Nurse Action 3". Accordingly, the care giver would then perform the protocol for Nurse Action 3 (found in FIG. 3, with text in
- 10 Section 3 of Table 1). The results indicated above for "Granulating Tissue" (3) and "Peripheral Edema" (1) both require Nurse Action 4, however such multiple indications for any given Action do not increase the number of times the Action must be performed (i.e. in this example, Nurse Action 4 is performed once, not twice). Finally, the marker for "Pain @ Wound" (4) intersects an arrow that points to Nurse Action 6. Thus, in
- 15 following the example above, the care giver would circle and perform Nurse Actions 2, 2C, 3, 4, and 5 as indicated in FIG. 3 by circles 32.

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Table 1: Possible text for modular wound care protocol Sheet (FIG. 3)

Table 1, SECTION 1	
1	<p>*GOAL* Maintain intact skin: Beware of deep tissue damage that may be irreversible.</p> <p>Assess knowledge of patient/caregiver on risk of skin breakdown and methods of prevention.</p> <p>Reduce effect of risk factors.</p> <p>Pressure: regular repositioning and pressure distribution (pillows, devices)</p> <p>Shear/friction: Apply protective ointment or moisture retentive dressing to reduce friction</p> <p>Excess Moisture: Clean at routine intervals with a skin cleanser, pat dry.. Protect skin from moisture and irritants with a moisture barrier and/or absorbent dressings/absorbent products.</p> <p>Dryness: Follow routine bathing procedure with gentle cleansers. Moisturize immediately after bathing. Apply body cream for areas prone to extreme dryness.</p> <p>Trauma/Skin Tears: Apply protective coverings to protect against friction and/or pressure</p> <p>Nutrition altered: Nutritional Support</p> <p>Action Taken _____</p>
	<p><input type="checkbox"/> Aloe Vesta 2-n-1 Skin Perineal/Skin Cleanser <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p> <p>Moisture Barriers</p> <p><input type="checkbox"/> Aloe Vesta 2-n-1 Protective Ointment <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Sensi-Care Protective Barrier <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p> <p>Skin Moisturizers</p> <p><input type="checkbox"/> Aloe Vesta 2-n-1 Skin Conditioner <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Sensi-Care Protective Barrier <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p> <p>Moisture Retentive Dressings</p> <p><input type="checkbox"/> DuoDERM Extra Thin _____ Size _____ <i>Days Used</i> M T W T F S S</p> <p>Absorbent Dressings</p> <p><input type="checkbox"/> Lyofoam _____ Size _____ <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Hydrosorb _____ Size _____ <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ Size _____ <i>Days Used</i> M T W T F S S</p> <p>Protective Coverings</p> <p><input type="checkbox"/> Tubifast <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Tubipad <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Arthropad <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p>
	<p>SKIN CARE PRODUCTS:</p> <p>Patient Bathing</p> <p><input type="checkbox"/> Aloe Vesta 2-n-1 Body Wash/Shampoo <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Sensi-Care Perineal/Skin Cleanser <i>Days Used</i> M T W T F S S</p>

Table 1, SECTION 2	
2	*GOAL* Obtain a clean wound bed.
PRODUCTS: <u>Wound Cleansing</u> <input type="checkbox"/> SAF Clens <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S	
2A	*GOAL* Provide moist wound environment.
PRODUCTS: <u>Primary Dressing</u> <u>Moisture Retentive Dressing</u> <input type="checkbox"/> DuoDERM CGF Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ Size _____ <i>Days Used</i> M T W T F S S <u>Secondary Dressing</u> Not applicable.	
2C	*GOAL* Absorb excess exudate/maintain moist wound environment.
PRODUCTS: <u>Primary Dressing</u> <u>Exudate Management</u> <input type="checkbox"/> AQUAGEL Hydrofiber Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Kaltostat Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Lyofoam Foam Dressing Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S <u>Secondary Dressing</u> <u>Moisture Retentive Dressing</u> <input type="checkbox"/> DuoDERM CGF Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ Size _____ <i>Days Used</i> M T W T F S S PRODUCTS:	
2B	*GOAL* Assist in autolytic debridement and removal of necrotic tissue / Provide moist wound environment.
PRODUCTS: <u>Primary Dressing</u> <u>Wound Hydration</u> <input type="checkbox"/> DuoDERM Hydroactive Gel <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S <u>Secondary Dressing</u> <u>Moisture Retentive Dressing</u> <input type="checkbox"/> DuoDERM CGF Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ Size _____ <i>Days Used</i> M T W T F S S	

Table 1, SECTIONS 5 AND 6	
5	*GOAL* .Prevent further skin breakdown and stimulate healing.
Relieve pressure PRESSURE ULCER --institute turning schedule for patient --utilize pressure reduction device(s) Action Taken and Products Used _____ _____	
<input type="checkbox"/> Bed/Mattresses _____ <input type="checkbox"/> Devices _____ <input type="checkbox"/> Other _____	
VENOUS STASIS ULCER Compression Therapy (30-40mm/Hg pressure to heal ulcer)	
PRODUCTS: <input type="checkbox"/> SurePress™ High Compression Bandage <input type="checkbox"/> SurePress Absorbent Padding <input type="checkbox"/> UNNA-FLEX <i>Days Used</i> M T W T F S S	
DIABETIC FOOT ULCERS Off loading of pressure	Action Taken and Products Used _____ _____
6	*GOAL* Pain Management
Provide analgesics. Cover with Moisture Retentive Dressings. Action Taken and Products Used _____ _____	

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Table 2: Possible text for modular wound care protocol Sheet (FIG. 3)

Nurse Action Report (Care Plan) Circle or check off the appropriate treatments and indicated products used.

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Solutions for Wound Treatment

Table 2, SECTION 1	
1	<p>*GOAL* Maintain intact skin: Beware of deep tissue damage that may be irreversible.</p> <p>Assess knowledge of patient/caregiver on risk of skin breakdown and methods of prevention.</p> <p>Reduce effect of risk factors.</p> <p>Pressure: regular repositioning and pressure distribution (pillows, devices)</p> <p>Shear/friction: Apply Skin Care products (lubricate) <i>or</i> Moisture Retentive Dressing (reduce friction)</p> <p>Excess Moisture: Manage with Skin Care Products or Moisture Retentive Dressing (protection) and incontinence products</p> <p>Dryness: Use Skin Care bathing and protection products.</p> <p>Nutrition altered: Nutritional Support</p> <p>Action Taken _____</p> <p>_____</p>
	<p>PRODUCTS:</p> <p>Patient Bathing</p> <p><input type="checkbox"/> Aloe Vesta Body Wash/Shampoo <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Septi-soft Body Wash/Shampoo <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p> <p>Skin Protection</p> <p><input type="checkbox"/> Aloe Vesta Skin Cream <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Aloe Vesta Protective Ointment <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p> <p>Incontinence Care</p> <p><input type="checkbox"/> Aloe Vesta Antifungal Ointment <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Aloe Vesta Protective Ointment <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Aloe Vesta Perineal Foam <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Aloe Vesta Perineal Solution <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Ilex Skin Protectant Paste <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p>

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Table 2, SECTIONS 2 and 3 - Debride Necrotic Tissue

2	Debride necrotic tissue.	
3	*GOAL* Provide systematic support/preventive measures to facilitate healing based on general patient assessment findings	
3	Wound Cleansing.	3A Moisture Retention
PRODUCTS: <input type="checkbox"/> Saline <i>Days Used</i> M T W T F S S <input type="checkbox"/> SAF Clens <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S		Primary Dressing: PRODUCTS: <input type="checkbox"/> DuoDERM CGF <i>Days Used</i> M T W T F S S <input type="checkbox"/> DuoDERM Extra Thin <i>Days Used</i> M T W T F S S <input type="checkbox"/> Signadress <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S Secondary Dressing: N/A
3B	Wound Hydration	3C Exudate Management
Primary Dressing: Wound Hydration: PRODUCTS: <input type="checkbox"/> DuoDERM Hydroactive CGF <i>Days Used</i> M T W T F S S <input type="checkbox"/> SAF Gel <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S Secondary Dressing: Moisture Retentive Dressing: PRODUCTS: <input type="checkbox"/> DuoDERM CGF <i>Days Used</i> M T W T F S S <input type="checkbox"/> DuoDERM Extra Thin <i>Days Used</i> M T W T F S S <input type="checkbox"/> Signadress <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S		Primary Dressing: Exudate Management: PRODUCTS: <input type="checkbox"/> Aquacel Hydrofiber <i>Days Used</i> M T W T F S S <input type="checkbox"/> Kaltostat Dressing <i>Days Used</i> M T W T F S S <input type="checkbox"/> Carboflex Odor <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S Secondary Dressing: Moisture Retentive Dressing: PRODUCTS: <input type="checkbox"/> DuoDERM CGF <i>Days Used</i> M T W T F S S <input type="checkbox"/> DuoDERM Extra Thin <i>Days Used</i> M T W T F S S <input type="checkbox"/> Signadress <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S

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Table 2, SECTIONS 4, 5, 6, and 7

4	*GOAL* Reduce devitalized tissue.		
<p>Debridement: The suggested topical treatments will facilitate autolytic debridement. Autolytic debridement is usually not recommended for patients with infected wounds or patients at increased risk of infection.</p> <p><input type="checkbox"/> Surgical by <input type="checkbox"/> MD <input type="checkbox"/> Nurse <input type="checkbox"/> Enzymatic</p> <p><i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Autolytic <input type="checkbox"/> Mechanical</p> <p>Products Used</p> <p>_____</p> <p>_____</p>			
5	If infection is confirmed, perform Nurse Action 5A. If infection is not confirmed, perform Nurse Action 5B.		
5A		5B	
Appropriate medical treatment for infection should be initiated or continued. DuoDERM CFG dressings can be continued during the treatment of infection at the discretion of the clinician.		Evaluate for signs of infection. If not infected, moisture retentive dressing should extend beyond reddened area to protect skin. Minimize friction and shear forces to surrounding skin.	
<p>Action Taken and Products Used to Treat Infection</p> <p>_____</p> <p>_____</p> <p>_____</p>			
6	Relieve Pressure	7	Provide analgesics. Cover with Moisture Retentive Dressings.
<p>Action Taken and Products Used</p> <p>_____</p> <p>_____</p> <p>_____</p>		<p>Action Taken and Products Used</p> <p>_____</p> <p>_____</p> <p>_____</p>	

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Table 2, SECTION 7

8	<p>Has the patient been screened for nutritional deficiency indicators in the past month.</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes → Rescreen Monthly</p> <p>↓</p> <p>Evaluate the patient for presence of any of the following nutritional deficiency indicators.</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><input type="checkbox"/> Elderly</p> <p><input type="checkbox"/> Infection</p> <p><input type="checkbox"/> Wound</p> <p><input type="checkbox"/> Systemic</p> <p><input type="checkbox"/> Other _____</p> <p><input type="checkbox"/> Score of <18 on Braden Scale</p> <p><input type="checkbox"/> Poor response to current wound treatment for past 2-4 weeks</p> <p><input type="checkbox"/> Recent unintentional weight loss/gain</p> </div> <div style="width: 45%;"> <p><input type="checkbox"/> Functional limitations</p> <p><input type="checkbox"/> Chewing/swallowing</p> <p><input type="checkbox"/> Mobility</p> <p><input type="checkbox"/> Hearing/speech</p> <p><input type="checkbox"/> Vision</p> <p><input type="checkbox"/> Dexterity</p> <p><input type="checkbox"/> Altered mental state</p> <p><input type="checkbox"/> Medical Condition</p> <p><input type="checkbox"/> Diabetes</p> <p><input type="checkbox"/> Arterial Insufficiency</p> <p><input type="checkbox"/> Cardiovascular disease</p> <p><input type="checkbox"/> Venous Insufficiency</p> <p><input type="checkbox"/> Incontinence</p> <p><input type="checkbox"/> Gastrointestinal disorder</p> <p><input type="checkbox"/> Immunosuppression</p> <p><input type="checkbox"/> Drug Therapy</p> <p><input type="checkbox"/> Corticosteroids</p> <p><input type="checkbox"/> Immunosuppressants</p> <p><input type="checkbox"/> Antitumor agents</p> </div> </div> <p>If any of the above is checked, perform Nutrition Assessment .</p>	
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Example 2 - Wound Prevention

- 5 One example of a method for assessing the status of a patient and derivation of a care plan, or protocol, for wound prevention is as follows. A Patient Risk Assessment Evaluation Sheet (FIG. 4), a type of interactive visual scoring sheet, is completed by a care giver using a variation of the Braden Scale by circling appropriate assessment scores for each risk factor (sensory perception, moisture, activity, mobility, nutrition and
- 10 friction & shear). Second, the Slide Rule Pressure Ulcer Pathway Decision Tool of FIG. 5 is used as follows: the slide rule is moved to each respective checked score from the Patient Risk Assessment Record (FIG. 4) for each respective risk factor. The arrows downward in the slide rule are followed to select the nurse actions (letters A to X) that correspond with the information contained in the Patient Risk Assessment Record.
- 15 Finally, all letters in the a modular wound prevention protocol sheet (also called a Nurse Action Report, FIG. 6) selected from the slide rule are circled. Circled protocols are then

followed. Table 3 provides the text of protocols that can be arranged on a single wound prevention protocol sheet, as shown schematically in FIG. 6.

- The method of practicing the invention is outlined in the example below. The care giver obtains the Patient Risk Assessment Record (FIG. 4) and the Slide Rule Pressure Ulcer Pathway Decision Tool of FIG. 5, and then examines a patient. The care giver obtains the following assessments: Sensory Perception = 3; Moisture = 1; Activity = 2; Mobility = 2; Nutrition = 4; Friction & Shear = 3. After recording this assessment on the Patient Risk Assessment Record (FIG. 4), the care giver follows any arrows in FIG. 4. Specifically, the Moisture grading of 1 points to "See Moisture Chart", the Activity grading of 2 points to "See Activity Chart", the Nutrition grading of 4 has no arrows and the Friction & Shear grading of 3 has no arrows.

- The care giver then uses the Slide Rule Pressure Ulcer Pathway Decision Tool of FIG. 5, and follows the decision tree for moisture. The first and second sliding cards 22e, 22f of FIG. 5 are displayed in FIG. 5B. Answering all questions, the care giver performs all nurse actions that apply. For instance, if the patient does not suffer urinary or fecal incontinence, but does perspire the care giver would perform Nurse Action F, but not nurse actions A, B, C, D, or E. Further consulting FIG. 5, the care giver slides the sliding card to an Activity rating of 2 and follows the arrows and protocols indicated in the view window (namely Nurse Action K, but not Nurse Action J since the Braden Scale total score is 15 for this patient). The care giver then slides the sliding card until the grade of 3 for nutrition number is indicated in the view window. The care giver then follows protocols indicated in the Nutrition window. For the patient above, given that the patient is only fed orally, Nurse Action P would be performed by the care giver, but not Nurse Actions O or V. The care giver then consults the Friction and Shear section of FIG. 5. Noting that a score of 3 for Friction & Shear does not appear with any arrows, no further Nurse Action protocols need be performed. Thus, for the patient of this example, as shown in the Nurse Action Report Sheet (FIG. 6), Nurse Action protocols F, K and P should be performed by the care giver.

Table 3: Possible text for modular wound prevention protocol sheet (FIG. 6)**Nurse Action Report**

Circle or check off the appropriate treatments and indicate products

used.

5

Table 3, Section 1: Managing Moisture

A. If related to tube feeding, lower volume, increase delivery time, decrease osmolality, add filler or add bulking agent. (*Consult dietary plan*). If nutritional intake is entreal, determine potential causes of loose stool. Check for impaction. If frequent, apply fecal incontinence pouch. If persistent, obtain order for anti-diarrheal medication.

☐ Products used

B. Cleanse skin promptly and thoroughly with incontinence skin cleanser or non-drying soap and pat dry.

☐ Aloe Vesta Perineal Solution

☐ Aloe Vesta Perineal Foam

☐ Other _____

C. If taking diuretic, schedule in late afternoon. If moisture is due to regular nighttime urinary incontinence, consider one scheduled toileting during the night.

D. Implement q 2h toileting schedule (waking hours) and offer fluids every 2 hours during waking hours. Cleanse skin promptly with non-drying soap or incontinence skin cleanser, pat dry. Use moisture barrier to protect skin. Use only underpads that wick fluid away from the skin, leaving surface next to skin dry. Cleanse skin, incontinence cleanser or non-drying soap.

☐ Aloe Vesta Perineal Solution

☐ Aloe Vesta Perineal Foam

☐ Aloe Vesta Protective Ointment

☐ Other _____

E. Use moisture barrier to protect surrounding tissue. Pouch heavily draining wound (Consult ET).

☐ Aloe Vesta Protective Ointment

☐ Other _____

F. Check linens every two hours. Change linens as needed. Bathe daily to remove waste products left by perspiration. Clean skin folds thoroughly, but gently and pat dry. Consider different mattress or support surface if a non-breathable covering is aggravating problem.

☐ Septi Soft Body Wash & Shampoo

☐ Other _____

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Table 3, Section 2: Activity

G. Implement plans for small shift in position.

H. Use pressure reducing chair seating. Implement q 1h chair repositioning schedule.

☐ Positioning Cushion

I. Teach patient to do lift-off's 15 minutes.

J. When in bed, use foam wedges for lateral position and pillow to bridge sacrum. Avoid lateral positioning of more than 30 degrees.

☐ Positioning Cushion
☐ Pillow
☐ Other _____

K. Place pressure reducing surface on bed or chair. Avoid positioning directly on trochanter.

☐ Mattress Overlay
☐ Positioning Cushion
☐ Other _____

L. When in bed, use positioning devices to suspend heels so they do not touch the mattress. Use good positioning to keep knees from touching. Avoid elevating HOB more than 30 degrees, except for brief periods.

☐ Positioning Cushion
☐ Other _____

M. Use pressure reducing chair seating. Implement q 1h chair repositioning schedule.

☐ Positioning Cushion
☐ Other _____

N. Implement q 2h turning schedule. If patient can make purposeful movements, encourage frequent turning/shifts in body position.

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Table 3, Section 3: Managing Nutrition

O. If dietician was not consulted to determine the match between the patient condition, metabolic need, and formula type and amount - initiate dietary consult to do so now.

P. Give protein supplement at bedtime.

☐ Protein Supplement

Q. If the patient is receiving less than optional amount because of high residual volumes in stomach, notify physician and obtain medication orders to decrease gastric retention or obtain orders for parental nutrition.

If the patient is receiving less than the optimal amount because of inadequate ordering or changes in patient's condition, request new orders from physician or dietician.

R. Request order for multi-vitamin with Vitamins A, C, and Zinc. Obtain dietary consult if these interventions are not successful within 24 hours. Change diet to reflect food preferences/habits or to address any problems with chewing or swallowing. Create caloric intake plan and monitor goal achievement.

☐ Vitamin Supplement

S. Attempt protein supplement at meals and before bedtime.

☐ Protein Supplement

T. Give supplement twice a day.

☐ Protein Supplement

☐ Other _____

U. Initiate physician contact to clarify goals of treatment and/or to examine avenues to improve nutritional intake.

V. Reassess periodically if patient's condition changes.

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Table 3, Section 4: Friction & Shear

W. Avoid raising HOB > 30 degrees. Use lifting sheet to move patient in bed; do not drag patient across the linens. Use elbow and heel protectors if these prominences are exposed to friction. Use a sheepskin under spastic extremities. (Do not place under trunk.)

- ☐ Positioning Cushion
☐ Heel or Elbow Protectors

X. Consider a trapeze, if patient has sufficient upper body strength to assist in moves.

Patient _____ Date: _____

Nurse _____ Physician _____

Notes _____

Further information for products referred to in the above table is listed below.

- 5
- AQUACEL Hydrofiber: a wound dressing comprising a non-woven pad composed of sodium carboxymethylcellulose fibers. The dressing is highly absorbent and forms a soft gel which interacts with wound exudate and forms a soft gel which maintains a moist environment for wound healing.
- 10
- Arthropad: Tubigrip Arthropad is a wrapping bandage designed to provide lasting, effective support with complete freedom of movement for the patient. The Tubigrip Arthropad provides tissue support in the management of soft-tissue injuries and general edema and may be used as a pressure dressing.
- 15
- Carboflex Odor: A sterile non-adhesive dressing with an absorbent wound contact layer (containing Alginate and Hydrocolloid), an activated charcoal pad and a smooth water-resistant top layer.
- 20
- DuoDERM Extra Thin: highly flexible, control gel formula dressing made for use on dry to lightly exuding wounds. The dressing conforms to the body,

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cleans by autolytic debridement and is a highly effective secondary dressing for wound fillers.

- 5 • DuoDERM Hydroactive Gel: a sterile gel comprising natural hydrocolloids (pectin, sodium carboxymethylcellulose) in a clear, viscous vehicle.
- 10 • DuoDERM Hydroreactive Gel: a sterile gel composed of natural hydrocolloids (pectin, sodium carboxymethylcellulose) in a clear, viscous vehicle. This product is designed for the management of partial and full-thickness wounds and creates a moist healing environment around a wound which helps to promote the natural autolytic process of debridement.
- 15 • DuoDERM CGF: is a dressing that interacts with wound exudate to produce a soft mass that enables removal of the dressing with little or no damage to newly formed tissues. The dressing helps isolate the wound against bacterial, viral (HIV-1 and HBV) and other external contamination and can remain in place up to seven days.
- 20 • Kaltostat: a sterile non-woven dressing of calcium-sodium alginate fiber which can absorb wound exudate or saline and convert from a firm gel/fiber mat. The gel forms a moist, warm environment at the wound interface.
- 25 • Kalostat Dressing: a highly absorbent calcium alginate dressing derived from natural seaweed designed to absorb exudate and control minor bleeding. The dressing is easy to apply, can remain in place up to seven days, and may be used on moderately to heavily exuding wounds.
- 30 • Lyofoam Foam Dressing: A polyurethane foam dressing comprising an absorptive hydrophilic contact surface and a secondary outer foam layer through which the aqueous component can be lost by evaporation. The dressing is freely permeable to gases and water vapor but resists strike-through of aqueous solutions and exudate, as the outer layer has hydrophobic properties.
- 35 • SAF Gel: an alginate containing formulation designed for multiple uses. The gel is indicated for use on chronic and acute wounds such as dry wounds, pressure ulcers (Stages I to IV) and stasis ulcers.
- 40 • SAF Clens: a wound cleaner that has a dual surfactant formulation designed for cleansing of chronic wounds, including superficial, partial-thickness, dry or necrotic wounds. The wound cleanser is nontoxic, nonirritating and comes in no-rinse formula.
- 45 • Signadress: a hydrocolloid dressing comprising an inner (wound contact) layer of hydrocolloids contained within an adhesive polymer matrix and an outer layer of polyurethane film. The dressing also has a product identification mark (ConvaTec registered tear drop trademark) and a visible (SignaDRESS) change indicator guide printed on the film backing.

- Sure Press High Compression Bandage and Sure Press Absorbant Padding: The SurePress High Compression Bandage System is comprised of two layers: the SurePress High Compression Bandage, a washable bandage made from high-quality blend of cotton-viscose, nylon and LYCRA, and the SurePress Absorbent Padding for use as an underlayer. The System can be used for management of venous leg ulcers and associated conditions, and is contraindicated for the management of arterial and mixed venous/arterial ulcers and legs with an ankle circumference less than 18 cm.
- Tubipad: is made from a layer of polyurethane foam banded to a length of elastic tubular bandage that is used for the protection of heels, elbows and knees.
- UNNA-FLEX: is an elastic bandage that provides compression, for instance to improve venous return. The bandage can be self-adherent or in the form of a boot.

One will appreciate that products listed in the table above, or functional equivalents, are commercially available from a variety of vendors.

All publications and references, including but not limited to patents and patent applications, cited in this specification are herein incorporated by reference in their entirety as if each individual publication or reference were specifically and individually indicated to be incorporated by reference herein as being fully set forth. Any patent application to which this application claims priority is also incorporated by reference herein in its entirety in the manner described above for publications and references.

While this invention has been described with an emphasis upon preferred embodiments, it will be obvious to those of ordinary skill in the art that variations in the preferred devices and methods may be used and that it is intended that the invention may be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications encompassed within the spirit and scope of the invention as defined by the claims that follow.